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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,954	07/22/2002	Stephen Arkinstall	ARKINSTALL=1	4903
	7590 07/09/200 D NEIMARK, P.L.L.C	EXAMINER		
624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	
			MAIL DATE	DELIVERY MODE
			07/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)					
Office Action Comments	10/070,954	ARKINSTALL ET AL.					
Office Action Summary	Examiner	Art Unit					
	Brenda L. Coleman	1624					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1)⊠ Responsive to communication(s) filed on <u>27 Ju</u>	ne 2008						
,— · · · · · · · · · · · · · · · · · · ·	action is non-final.						
<i>i</i> —		secution as to the marits is					
· · ·	) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
closed in accordance with the practice under L.	x parte Quayle, 1935 C.D. 11, 40						
Disposition of Claims							
4)⊠ Claim(s) <u>1-3,5-12,20-22,27-31,35 and 36</u> is/are	pending in the application.						
4a) Of the above claim(s) is/are withdraw	4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.	_						
6)⊠ Claim(s) <u>1-3,5-12,20-22,27-31,35 and 36</u> is/are	rejected.						
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/or	election requirement						
o) Claim(o) and dubject to rectnetion and, or	oloolon roquiromoni.						
Application Papers							
9) The specification is objected to by the Examiner	r.						
10) The drawing(s) filed on is/are: a) acce	epted or b) objected to by the E	Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)□ Some * c)□ None of:							
<ol> <li>Certified copies of the priority documents</li> </ol>	1. Certified copies of the priority documents have been received.						
<ol><li>Certified copies of the priority documents</li></ol>	2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
Attachment(s)							
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)							
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date.							
3) Information Disclosure Statement(s) (PTO/SB/08)  5) Notice of Informal Patent Application							
Paper No(s)/Mail Date 6) U Other:							

## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Claims 1-3, 5-12, 20-22, 27-31, 35 and 36 are pending in the application.

This action is in response to applicants' amendment dated May 27, 2008. Claims 2, 9, 11 and 21 have been amended.

## Response to Amendment

Applicant's arguments filed May 27, 2008 have been fully considered with the following effect:

1. With regards to the provisional obviousness-type double patenting rejection of claims 1-3 and 5-41 labeled paragraph 1) over copending Application No. 10/381,200 maintained in the last office action, the applicants requested that this rejection be held in abeyance at this time.

Claims 1-3, 5-12, 20-22, 27-31, 35 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No, 10/381,200, for reasons of record and stated above.

2. With regards to the provisional obviousness-type double patenting rejection of claims 1-3 and 5-41 labeled paragraph 2) over copending Application No. 10/381,665

maintained in the last office action, the applicants requested that this rejection be held in abeyance at this time.

Claims 1-3, 5-12, 20-22, 27-31, 35 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No, 10/381,665, for reasons of record and stated above.

- 3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claim 11, labeled paragraph 6) of the last office action, which is hereby **withdrawn**.
- 4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections of claims 9, 21 and 22, labeled paragraph 7) of the last office action, which are hereby **withdrawn**.

In view of the amendment dated May 27, 2008, the following new grounds of rejection apply:

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There are several species which are not described in the specification, i.e. the 5<sup>th</sup> species on page 14 "methyl 3-({1-[(5-{[(4-chlorobenzoyl)amino]-methyl}thien-2-yl)sulfonyl]piperidin-4-yl}amino)-benzoate; the 1<sup>st</sup> species on page 20 "methyl 3-{[1-({5-[({3-nitrobenzoyl}amino)methyl]-thien-2-yl}sulfonyl)-piperidin-4-yl]amino}benzoate; the last species at the bottom of page 21 "methyl 3-{[1-({5-[({4-nitrobenzoyl}amino)methyl]-thien-2-yl}sulfonyl)piperidin-4-yl]amino}benzoate; and the 4<sup>th</sup> species on page 28 "methyl 3-({1-[(5-{[({3-methoxybenzoyl})amino]-methyl}thien-2-yl)sulfonyl]piperidin-4-yl}amino)-benzoate.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 6. Claims 2, 3, 11, 12, 21, 22 and 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:
  - a. Claims 2, 3, 29, 30 and 31 are vague and indefinite in that it is not know what is meant by the superscript "2" which appears after the Ar<sup>1</sup> and Ar<sup>2</sup> are in the 3<sup>rd</sup> from the last line on page 3 of the amendment.
  - b. Claim 11 recites the limitation "tert-butyl ....carbamate" in the 4<sup>th</sup> species on page 10. There is insufficient antecedent basis for this limitation in the claim.
  - Claim 11 recites the limitation "benzyloxy" in the 7<sup>th</sup> species on page 10.
     There is insufficient antecedent basis for this limitation in the claim.

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d. Claim 11 recites the limitation "phenoxy" in the 5<sup>th</sup> species on page 11.

There is insufficient antecedent basis for this limitation in the claim.

- e. Claim 11 recites the limitation "1,3-dithiolan-2-yl" in the 7<sup>th</sup> species on page 15. There is insufficient antecedent basis for this limitation in the claim.
- f. Claim 11 recites the limitation "amino(imino)methyl" in the 2<sup>nd</sup> species on page 16. There is insufficient antecedent basis for this limitation in the claim.
- g. Claim 11 recites the limitation "2,2-dioxido-1,3-1,3-dihydro-2-benzothien-5-yl" in the 4<sup>th</sup> species on page 17. There is insufficient antecedent basis for this limitation in the claim.
- h. Claim 11 recites the limitation "2,3-dihydro-1H-inden-5-yl" in the 5<sup>th</sup> species on page 17. There is insufficient antecedent basis for this limitation in the claim.
- i. Claim 11 recites the limitation "morpholino" in the 1<sup>st</sup> species on page 18.
   There is insufficient antecedent basis for this limitation in the claim.
- j. Claim 11 recites the limitation "3-cyclohexyl" in the 3<sup>rd</sup> species on page 18.
   There is insufficient antecedent basis for this limitation in the claim.
- k. Claim 11 recites the limitation "(butylamino)sulfonyl" in the 4<sup>th</sup> species on page 18. There is insufficient antecedent basis for this limitation in the claim.
- I. Claim 11 recites the limitation "4-(5,6,7,8-tetrahydronaphthalen-1ylamino)" in the 6<sup>th</sup> species on page 18. There is insufficient antecedent basis for this limitation in the claim.

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m. Claim 11 recites the limitation "aminosulfonyl" in the 7<sup>th</sup> species on page
 18. There is insufficient antecedent basis for this limitation in the claim.

- n. Claim 11 recites the limitation "3-propylphenoxy" in the 10<sup>th</sup> species on page 18. There is insufficient antecedent basis for this limitation in the claim.
- Claim 11 recites the limitation "aminosulfonyl" in the 10<sup>th</sup> species on page
   There is insufficient antecedent basis for this limitation in the claim.
- p. Claim 11 recites the limitation "aminosulfonyl" in the 9<sup>th</sup> species on page
   21. There is insufficient antecedent basis for this limitation in the claim.
- q. Claim 11 recites the limitation "1,3-dithiolan-2-yl" in the 10<sup>th</sup> species on page 22. There is insufficient antecedent basis for this limitation in the claim.
- r. Claim 11 recites the limitation "amino(imino)methyl" in the 1<sup>st</sup> species on page 23. There is insufficient antecedent basis for this limitation in the claim.
- s. Claim 11 recites the limitation "amino(imino)methyl" in the 6<sup>th</sup> species on page 23. There is insufficient antecedent basis for this limitation in the claim.
- t. Claim 11 recites the limitation "2,2-dioxido-1,3-1,3-dihydro-2-benzothien-5-yl" in the 8<sup>th</sup> species on page 23. There is insufficient antecedent basis for this limitation in the claim.
- u. Claim 11 recites the limitation "2,3-dihydro-1H-inden-5-yl" in the 9<sup>th</sup> species on page 23. There is insufficient antecedent basis for this limitation in the claim.
- v. Claim 11 recites the limitation "morpholin-4-yl" in the 8<sup>th</sup> species on page 24. There is insufficient antecedent basis for this limitation in the claim.

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w. Claim 11 recites the limitation "3-propylphenoxy" in the 9<sup>th</sup> species on page 24. There is insufficient antecedent basis for this limitation in the claim.

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- x. Claim 11 recites the limitation "2,3-dihydro-1H-inden-5-yl" in the 3<sup>rd</sup> species on page 25. There is insufficient antecedent basis for this limitation in the claim.
- y. Claim 11 recites the limitation "morpholin-4-yl" in the 1<sup>st</sup> species on page
   26. There is insufficient antecedent basis for this limitation in the claim.
- z. Claim 11 recites the limitation "3-cyclohexyl" in the 7<sup>th</sup> species on page 26.

  There is insufficient antecedent basis for this limitation in the claim.
- aa. Claim 11 recites the limitation "(butylamino)sulfonyl" in the 8<sup>th</sup> species on page 26. There is insufficient antecedent basis for this limitation in the claim.
- bb. Claim 11 recites the limitation "4-(5,6,7,8-tetrahydronaphthalen-1ylamino)" in the 10<sup>th</sup> species on page 26. There is insufficient antecedent basis for this limitation in the claim.
- cc. Claim 11 recites the limitation "3-propylphenoxy" in the 1<sup>st</sup> species on page 27. There is insufficient antecedent basis for this limitation in the claim.
- dd. Claim 11 recites the limitation "1,3-dithiolan-2-yl" in the 7<sup>th</sup> species on page 27. There is insufficient antecedent basis for this limitation in the claim.
- ee. Claim 11 recites the limitation "aminosulfonyl" in the 3<sup>rd</sup> species on page 28. There is insufficient antecedent basis for this limitation in the claim.
- ff. Claim 11 recites the limitation "1,3-dithiolan-2-yl" in the 1<sup>st</sup> species on page 29. There is insufficient antecedent basis for this limitation in the claim.

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gg. Claim 11 recites the limitation "amino(imino)methyl" in the 5<sup>th</sup> species on page 29. There is insufficient antecedent basis for this limitation in the claim.

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hh. Claim 11 recites the limitation "2,2-dioxido-1,3-1,3-dihydro-2-benzothien-5-yl" in the 7<sup>th</sup> species on page 30. There is insufficient antecedent basis for this limitation in the claim.

- ii. Claim 11 recites the limitation "2,3-dihydro-1H-inden-5-yl" in the 8<sup>th</sup> species on page 30. There is insufficient antecedent basis for this limitation in the claim.
- jj. Claim 11 recites the limitation "3-propylphenoxy" in the 5<sup>th</sup> species on page 31. There is insufficient antecedent basis for this limitation in the claim.
- kk. Claim 11 recites the limitation "morpholin-4-yl" in the 6<sup>th</sup> species on page 31. There is insufficient antecedent basis for this limitation in the claim.
- II. Claim 11 recites the limitation "3-cyclohexyl" in the 10<sup>th</sup> species on page
   31. There is insufficient antecedent basis for this limitation in the claim.
- mm. Claim 11 recites the limitation "(butylamino)sulfonyl" in the 1<sup>st</sup> species on page 32. There is insufficient antecedent basis for this limitation in the claim.
- nn. Claim 11 recites the limitation "4-(5,6,7,8-tetrahydronaphthalen-1ylamino)" in the 3<sup>rd</sup> species on page 32. There is insufficient antecedent basis for this limitation in the claim.
- oo. Claim 11 recites the limitation "hexyloxy" in the 9<sup>th</sup> species on page 32. There is insufficient antecedent basis for this limitation in the claim.

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pp. Claim 11 recites the limitation "aminosulfonyl" in the 8<sup>th</sup> species on page

- 33. There is insufficient antecedent basis for this limitation in the claim.
- qq. Claim 11 recites the limitation "1,3-dithiolan-2-yl" in the 9<sup>th</sup> species on page 34. There is insufficient antecedent basis for this limitation in the claim.
- rr. Claim 11 recites the limitation "amino(imino)methyl" in the 10<sup>th</sup> species on page 34. There is insufficient antecedent basis for this limitation in the claim.
- ss. Claim 12 recites the limitation "aminosulfonyl" in the 2<sup>nd</sup> species on page 36. There is insufficient antecedent basis for this limitation in the claim.
- tt. Claims 21 and 22 are vague and indefinite in that it is not know what is meant by the second occurrence of the moiety "substituted or unsubstituted cyclic  $C_4$ - $C_8$  alkyl optionally containing 1-3 heteroatoms and optionally fused with aryl or heteroaryl" in the definition of  $L^1$  and  $L^2$ .

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-3, 5-7, 9, 20 and 27-31 are rejected under 35 U.S.C. 102(e) as being anticipated by STEFFAN et al., U.S. 6,506,901. Steffan teaches the compounds and compositions of the compounds of formula I where Ar<sup>1</sup> is phenyl; X is O, R<sup>1</sup> is H; n is 1; Ar<sup>2</sup> is 2,5-thienylene; and Y is piperidino which is substituted by

as set forth in the Table spanning columns 169 and 170, labeled examples 179, 180, 181, 182 and 183.

8. Claims 1-3 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by MEDERSKI et al., WO 00/32577. Mederski teaches the compounds and compositions of the compounds of formula I where Ar<sup>1</sup> is naphthyl; X is O, R<sup>1</sup> forms a substituted 6-

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membered ring with Ar<sup>1</sup>; n is 0; Ar<sup>2</sup> is 1,5-napthylene; and Y is piperidino as set forth in Example 28 on pages 121-122, i.e.

$\mathbb{R}^i$ in $\mathbb{R}^i$ -H and in Ig	MS.	
	calculated	found
-NH-(CH <sub>2</sub> ) <sub>3</sub> -NH <sub>2</sub>	542	543
-NH-(CH <sub>2</sub> ) <sub>5</sub> -NH <sub>2</sub>	570	571
-NH- (CH <sub>2</sub> ) ?-NH <sub>2</sub>	······	
_N — сн <sub>2</sub> — Сн <sub>2</sub> — NН,	2.	

9. Claims 1-3 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by NEDOSPASOV et al., SU 1 706 174. Nedospasov teaches the compounds and compositions of the compounds of formula I where Ar<sup>1</sup> is phenyl; X is O, R<sup>1</sup> forms a substituted 5-membered ring with Ar<sup>1</sup>; n is 0; Ar<sup>2</sup> is 1,5-napthylene; and Y is piperidino as set forth in the compound with registry no. 176976-69-5, i.e.

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10. Claims 1, 3 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by PALAIMA et al., Chemija (CAPLUS printout herein provided). Palaima teaches the compounds of formula I where Ar<sup>1</sup> is phenyl; X is O, R<sup>1</sup> forms a substituted 5-membered ring with Ar<sup>1</sup>; n is 0; Ar<sup>2</sup> is 1,6-napthylene; and Y is piperidino as set forth in the compound with registry no. 145045-52-9, i.e.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/ Primary Examiner, Art Unit 1624